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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/554,315

10/24/2005

Shin-Jen Shiao

2698

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11/10/2011

EXAMINER

THOMAS, TIMOTHY P

ART UNIT

PAPER NUMBER

1628

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DELIVERY MODE

11/10/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/554,315

Applicant(s)

SHIAO, SHIN-JEN

Examiner

TIMOTHY THOMAS

Art Unit

1628

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 64-66, 68-71, 73, 77, 82-84 and 86-88 is/are pending in the application.
- 5a) Of the above claim(s) 66, 69, 73, 77 and 86 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 64, 65, 70, 71, 82-84 and 86-88 is/are rejected.
- 8) ☒ Claim(s) 64 and 82-84 is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☒ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-942)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date 10/24/2005
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION***Election/Restrictions***

1. Applicant's election with traverse of Group I in the reply filed on 8/8/2011 is acknowledged. The traversal is on the ground(s) that Ohashi et al. (US 6,297,244 B1) has nothing to do with this invention at all, because the acids taught are designated to be stabilizing agents for AS-3201, and do not concern any treatment of ailment at all; the present claims lower humoral pH and treat ailments; 2) the compound AS-3201 is taught to have potent aldose reductase inhibitory activity; there is no discussion about the disease treatment concerning the present invention in Ohashi; there is no purpose for the acids besides stabilizer; and phosphoric acid is never taught alone (without AS-3201). This is not found persuasive because the instant claim 64 is construed to require 0.06-100 wt% phosphoric acid and a pharmaceutical carrier. The record establishes this compound is taught in the recited amount, with the recited pharmaceutical carrier. Thus the required component is taught by this reference. It is noted that the language "in the treatment of allergies; by lowering humoral pH with edible acid or its acidic salt" is not given patentable weight. In response to applicant's argument, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the product taught contains the recited component, meeting the claim limitations.

With respect to the presence of the active agent, AS-3201, claim 64 uses open construction, i.e., "comprises", as the transitional phrase. This term has the meaning that the recited components of the claim are required, but other components may also be present. In other words, the presence of AS-3201 is not excluded from claim 64. It is not relevant that this compound is taught in the formulations. MPEP 2111.03 indicates:

The transitional phrases "comprising", "consisting essentially of" and "consisting of" define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Mars Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term 'comprising,' the terms 'containing' and 'mixture' are open-ended."); *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ... ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

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The requirement is still deemed proper and is therefore made FINAL.

2. Applicant's election with traverse of forms of health care foods in which phosphoric acid is contained in the reply filed on 10/17/2011 is acknowledged. The traversal is on the ground(s) that see arguments discussed above. This is not found persuasive because see response presented above.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 66, 68-69, 73, 77 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/17/2011.

4. It is noted that applicant's response is non-compliant, in that there was no election of a species under (iii) for a single ailment specie. However, in view of the multiple restriction requirements that have already been mailed, and in view of compact prosecution, it is noted that only three ailments remain in claims 86-88, which are recited only as intended uses of the pharmaceutical composition. Therefore, each of these is taken up for examination.

Priority

5. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in China on 4/26/2004 and applications filed with WIPO on 3/5/2004 and 11/4/2004. It is noted, however, that applicant has not filed certified copies of the CN, PCT or WO applications as required by 35 U.S.C. 119(b).

Specification

6. The disclosure is objected to because of the following informalities: the lines "Method lowers..." at p. 1, line 11; "Yet not any..." at p. 2, line 13; "Human body has the ability..." at p. 9, line 4; "It is provided the use..." at p. 10, line 12; "It is the principal object of this invention is to..." of p. 10, line 16; and p. 11, line 1 are grammatically incorrect.

Appropriate correction is required.

7. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

8. Claim 64 and 82-84 are objected to because of the following informalities: The language "0.06.about.100" in claim 64 is incorrect grammatically. Claims 82-84 should have the word "and" connecting the recited claims (i.e., "64, 86-87 and 88"). The word "bit" in claim 86 is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 64-65, 70-71, 82-84 and 86-88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 64 recites "0.06.about.100 wt %". This language does not have any meaning rendering the instant claims indefinite with respect to the required amount of compound. The language is construed, for the purpose of prior art application, to encompass the range from 0.06 to 100 wt %.

With respect to the 100 wt% endpoint of the range, this endpoint of the range is indefinite. It is not possible to have both 100 wt % of phosphoric acid AND a carrier. "100 wt%" means that phosphoric acid is the only component present; no other components can be present; i.e., this percentage is mutually exclusive of additional components. In conflict with this, the addition of a carrier is specifically required by claim 64. It is not clear whether the 100% or required carrier control the claim. This also renders all claims dependent on claim 64 as indefinite.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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12. Claims 64-65, 70-71, 82-84 and 86-88 are rejected under 35

U.S.C. 102(a) & (e) as being anticipated by Lee et al. (US 2004/0022921 A1; 2004 Feb; filed 2003; priority 2002).

Lee teaches a combination an acidulant system in lemon/lime flavored beverages; the acidulant system includes phosphoric acid and a buffer system that includes a phosphate salt (abstract); 1 L syrup for use in making lemon-lime flavored cola drink was prepared, the ingredients combined were (paragraph 0030):

TABLE 1

ingredient	(g)
sucrose	656.0
potassium benzoate	1.68
potassium citrate	2.0
disodium phosphate	2.0
citric acid	1.3
adipic acid	4.5
phosphoric acid	2.2
cola flavors	15.0
lemon flavors	12.0
purified water	Q. S. 1 L

The amount of phosphoric acid (2.2 g) and its sodium salt (disodium phosphate, 2.0 g) out of 1 L (about 1000 g) corresponds to about 0.42 wt % edible acid and its acidic salts of sodium. Purified water is present (a carrier). The flavored cola is a drink (i.e., an oral agent), and the cola, within the recited alternatives of claim 71, is also within the scope of the elected health care food, demonstrated by the dependency of cola of claim 71 on claim 70. Lee teaches a panel of cola experts tasted the lemon/lime flavored cola drinks made according to Example 1 (the

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composition was served to humans, i.e., taken to also read on “for animals” and “for mammal animals” in claims 82-83; paragraph 0041).

With respect to the recitation of “pharmaceutical”, the term is not considered to require any structural difference from the compositions taught by Lee; i.e., the compositions of Lee read on the recited “pharmaceutical” compositions. The intended use limitations: “in the treatment of allergies” in claim 1; “for use in the treatment of insect bit[e]” of claim 86; “for use in the treatment of inflammation” of claim 87, and “for use in the treatment of itch” of claim 88 are not given patentable weight. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the product taught contains the recited phosphoric acid component in applicant elected health care food (i.e., a cola) in the recited amounts, thus, meeting the recited component claim limitations.

Lowering pH is specifically taught, i.e., a 1:5 dilution of the syrup with carbonated water resulted in a pH of the cola drinks of 3.43 (paragraph 0031). pH 3.43 is lower than neutral pH. Thus, the “by lowering humoral pH” of claim 64 is considered to be characteristic of the formulations taught.

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are

newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Therefore, this formulation anticipates the instant claims.

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY THOMAS whose telephone number is (571)272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy P Thomas/
Primary Examiner, Art Unit 1628